CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CPRIT Product Development Program

FY 2020 Cycle 2 (20.2) TXCO, RELCO, SEED RFAs

Webinar: November 14, 2019

Cindy WalkerPeach, PhD
Chief Product Development Officer

Rosemary French, MBA
Senior Program Manager

Webinar Participants

Hosts:

Cindy WalkerPeach, PhD
Chief Product Development Officer

Rosemary French, MBA
Senior Program Manager

CPRIT Reviewers:

David Shoemaker, PhD
Deputy Chair, Product Development Review Council

Jim Jordan, MBA
Reviewer, Product Development

Agenda and Q&A

Agenda

- Overview – CPRIT Product Development Program and available RFA grant mechanisms (SEED, TXCO, RELCO)
- Live Q&A Session

Q&A

- Participant lines will be muted during the webinar.
- Participants may submit questions at any time.
- Questions will be addressed at the end of the presentation.
- Pease submit your questions using “Questions Box” on the GoToWebinar control panel and clicking SEND.

CPRIT Grant Award Data to 21Aug19

1,447 Awards Totaling $2.41 Billion

Academic Research
1,178 awards, $1.72 billion

Product Development Research
43 awards, $437.1 million

Prevention
226 awards, $250.0 million

Combined research awards:
1,221 awards, $2.16 billion

Clinical Research (31.1%)	$670.7 million
Translational Research (25.1%)	$540.6 million
Recruitment (26.7%)	$575.2 million
Basic Research (14.3%)	$308.9 million
Research Training (2.8%)	$ 59.9 million

2020 Product Development Program Priorities

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available; i.e**., disruptive technologies**
- Funding projects addressing large or challenging **unmet medical needs**
- Investing in **early-stage** projects when private capital is least available
- Stimulation commercialization of technologies developed at **Texas institutions**
- Supporting **new company formation in Texas or attracting promising companies to Texas** that will recruit staff with life science expertise, especially experienced C-level staff, to lead to seed clusters of life science expertise at various Texas locations
- Providing appropriate **return on Texas taxpayer investment**

Product Development Awards

- **Objectives**
  - Identifying and funding projects to develop **novel drugs, diagnostic applications, medical devices and other non-traditional products** with focused relevance to **cancer** research, treatment and prevention
  - Funding **Texas-based companies and companies willing to relocate to Texas** are most likely to bring important products to the market
  - Providing funding that promotes the **translation of research at Texas institutions into startup companies** able to compete in the marketplace
- **Product Development Awards to date**
  - **43 awards approved totaling $437.1 million**
  - **17 awardee companies conducting active clinical trials**
  - **More than $3.15 billion in follow-on funding**
  - **662 jobs created in Texas**

Product Development Investments

Lubbock

CerRx

Dallas

NEXEON

ONCOMANO

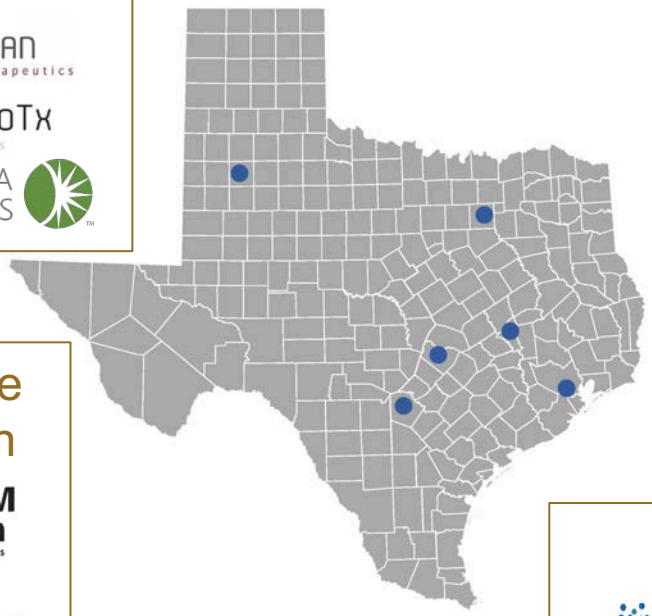
Peloton Therapeutics

San Antonio

PELICAN Therapeutics

NanoTx THERAPEUTICS

EMTORA BIOSCIENCES



College Station

FUJIFILM Diosynth biotechnologies

CALIBER biotherapeutics

Houston

aravive BIOLOGICS Outcompeting Cancer™

allo VIr

ALLterum Therapeutics

Bellicum PHARMACEUTICALS

Cell Medica

DNAtrix THERAPEUTICS

ESSA

Hummingbird BIOSCIENCE

immatics

InGeneron

INSTAPATH

Iterion

kealex THERAPEUTICS

Magnolia Tejas Corporation

MEDICENNA THERAPEUTICS CORP.

PERIMETER

PULMOTECT

Salarius PHARMACEUTICALS The Cancer Epigenetics Company

VISUALASE

Austin

aeglea BIOTHERAPEUTICS

apollo endosurgery

Asuragen

Curtana PHARMACEUTICALS

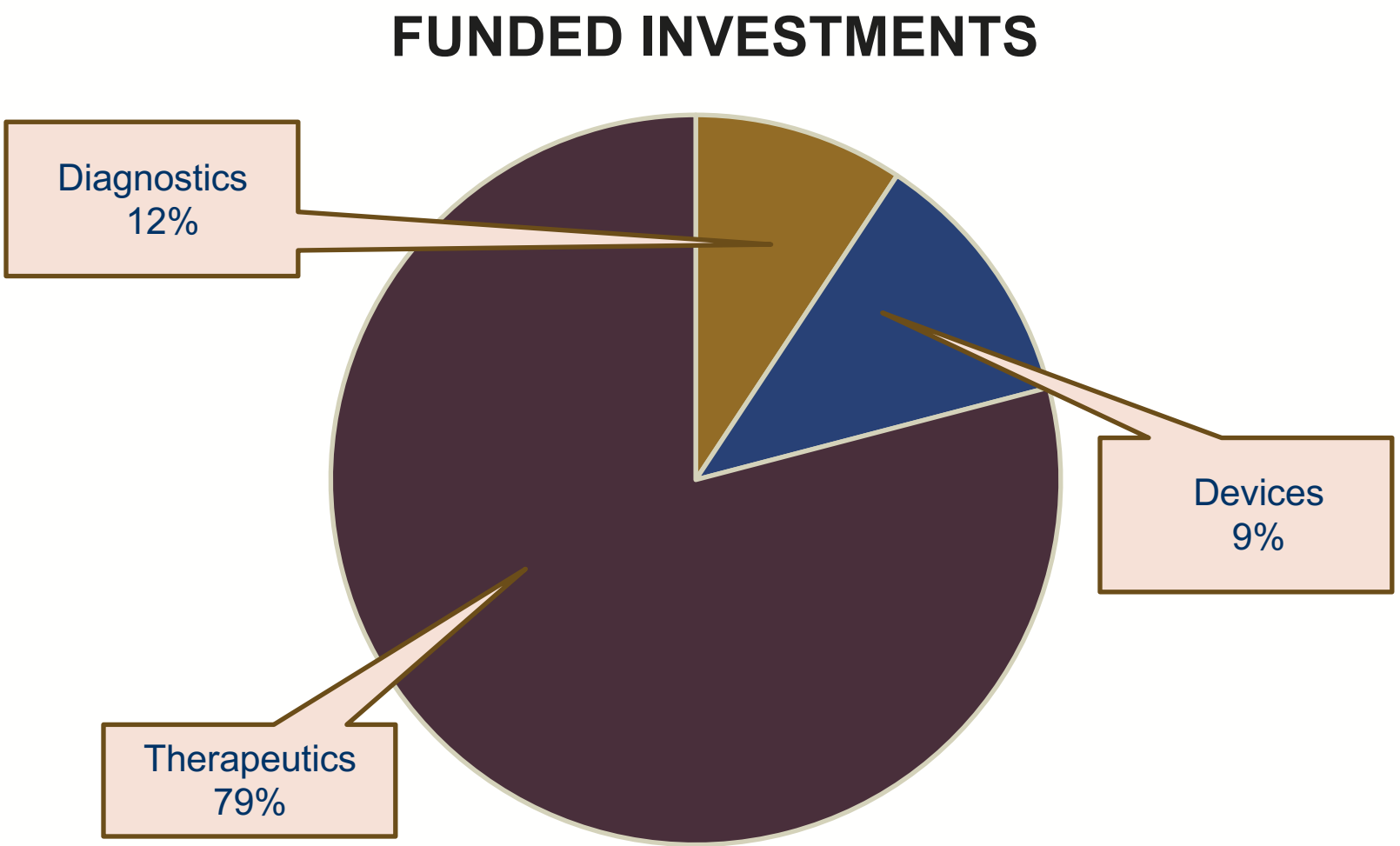
FORBIUS

tem MOLECULAR TEMPLATES

MYRIAD RBM

MiRNA THERAPEUTICS

Current Product Development Portfolio Mix



FY 2020 Cycle 2 Award Mechanisms

General Criteria

- Startup or established companies developing innovative products or services
- Significant potential impact on cancer patient care
- Scientific “Proof of Principle” demonstrated; business merit

Three Product Development Mechanisms

- **Texas Company Awards (TXCO)**
  - Startups or established companies located in Texas
  - Up to $20M over 36 months
- **Company Relocation Awards (RELCO)**
  - Startups or established companies willing to relocate to Texas
  - Up to $20M over 36 months
- **Seed Awards (SEED)**
  - Startup companies based in Texas or willing to relocate to Texas
  - Up to $3M over 36 months

Award Requirements, Part 1

- **Contracted relationship with CPRIT**
- **Annual Progress Report Review** – meet goals/objectives to continue funding tranches
- **50% match requirement**
  - For example, a company that applies for $1 million in CPRIT funding must raise $500,000 in external matching funds
- **Revenue sharing commitment included as part of contract**
  - **Therapeutics: 3-5% royalty until 4X the award amount paid to Texas. After 4X award amount is paid to Texas, royalty reduced to 0.5%.**
    - For example, therapeutics awardee that receives a $10 million CPRIT award pays 3-5% in royalties (depending on the amount of cumulative revenue) until the total royalty payments equal $40 million, at which point royalties would drop to 0.5%
  - **Devices/Diagnostics/Services: 3-5% royalty until 2.5X the award amount paid to Texas. Then royalty reduced to 0.5%.**
    - For example, diagnostics awardee that receives a $10 million CPRIT award pays 3-5% in royalties (depending on the amount of cumulative revenue) until the total royalty payments equal $25M million, at which point royalties would drop to 0.5%
  - **More details:** https://www.cprit.state.tx.us/our-programs/product-development-research/revenue-sharing/

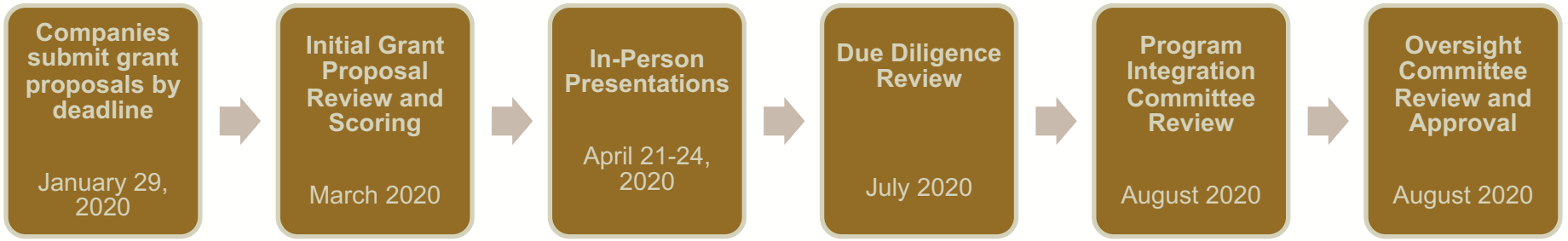
Award Requirements, Part 2

Texas Location Criteria

- **Awardees must:**
  - **either already be based in Texas or,**
  - **commit to become Texas-based upon receipt of award**
- **A company is considered to be Texas based if it fulfills or commits to fulfilling a majority of the following criteria:**
  1. The US headquarters are physically located in Texas.
  2. The Chief Executive Officer resides in Texas.
  3. A majority of the company's personnel, including at least 2 other C-level employees (or equivalent) reside in Texas.
  4. Manufacturing activities take place in Texas.
  5. At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
  6. At least 1 clinical trial site is in Texas.
  7. The company collaborates with a medical research organization in Texas, including a public or private institute of higher education.

Multi-Stage Review Process

FY 2020 Cycle 2



Reminder: Key Dates

FY 2020 Cycle 2

RFAs Released	November 20, 2019
Application Portal Opens	December 4, 2019
Applications Due	January 29, 2020
In-Person Presentation	April 21-24, 2020
Award Notification	August 2020

FY 2021 Cycle 1 (tentative)

RFA Release Date	Summer 2020
Applications Due	Summer 2020
Award Notification	February 2021

Reviewer Perspectives

David Shoemaker, PhD
Deputy Chair, Product Development Review Council

Jim Jordan, MBA
Reviewer, Product Development

Invest in Commercially Viable Projects

SEED Awards:

- Startups, early-stage commercial concept
- Novel technology, may not be completely at product stage
  - Drugs and Biologics, multiple candidates, no lead
  - Devices, early prototype, not fieldable
  - Diagnostics, may have a research test or LDT
- Strong value proposition with preliminary business plan
- Science-based personnel accessing commercial product development consultants
- Demonstrated understanding of the commercial product development process IND/IDE (clinical, preclinical, CMC, regulatory)

TXCO/RELCO Awards:

- Newly established or established companies
- Novel technology, more likely at product stage
  - Drugs and Biologics, established lead (IND within a year)
  - Devices, commercial-ready prototype (IDE within a year)
  - Diagnostics, commercial-ready prototype (IDE within a year)
- Viable commercial concept with strong Value Proposition and business plan
- Veteran, experienced product development team (fewer consultants)
- Veteran, experienced management team, likely to have secured independent funds
- Deep understanding of the of commercial product development process and marketplace (clinical, preclinical, CMC, regulatory, statistical, marketing, reimbursement, program management, post-market surveillance, competitive landscape, product life cycle, pipeline development, distribution strategy, partnering strategy)

SEED Early Development Stage Grant

- Startup companies
- ~2 - 3 years from filing IND/IDE
- Early Pharmacodynamic Proof of Concept
  - Supported by rigorous pharmacology data in multiple models
- Preliminary Preclinical Safety Data
  - Secondary pharmacology studies (specificity)
- Preliminary Development Plans (Clinical, Preclinical, CMC, Regulatory)
- Preliminary Commercialization Strategy
  - Preliminary understanding of competitive landscape and path to market

TXCO/RELCO Development Stage Grant

- Established company, one year from filing IND/IDE or in the Clinic
- Established Proof of Concept
- Completed Preliminary Assay Validation Work
- Completed Pilot Toxicology Studies (most sensitive species identified)
- Completed Initial CMC Studies (initial small-scale batches)
- Management and Disciplinary Expert Personnel (Medical/Clinical, Preclinical, CMC, Regulatory, Commercial) Employed or Identified
- Completed Target Product Profile and/or Integrated (Clinical, Nonclinical, CMC, Regulatory) Product Development Plan through to marketing application
- Completed Intellectual Property Strategy and Initial Filings
- Preliminary Commercialization Plan

What makes a strong device/diagnostic application?

	Medical Device	Diagnostic
Market potential	• ↑ $250 million segment	• ↑ $100 million segment
Sales & marketing (commercialization plan)	• ↑ New category or improvement of existing category • Direct or distribution strategy • Formulary & buying group strategy	• New category or test not offered by major Dx player • Direct or distribution strategy • Kit/product or CLIA
Technology & IP (development plan)	• Existing PCT's or patents • Adequate IP landscape analysis • Design system requirement plan	• Existing PCT's or patents • Trade secrets, proprietary know-how
Clinical evidence (clinical plan)	• Bench data • Biocompatibility analysis • Animal data and maybe FIH	• Human clinical data on sensitivity (w/ disease), & specificity (w/o) • Competitive comparable performance data if existing category, materiality if not
Regulatory & reimbursement	• Pathway: BLA, PMA, 510k • Existing DRG, ICD and/or CPT • Animal data and maybe FIH	• CLIA or PMA/510k pathway • Coding plan for Part A & Part B, new or existing
Team	• Technical team in place • Regulatory consultants engaged	• Technical team in place • Regulatory consultants engaged • CLIA experienced personnel in operations
Revenue	• None	• CLIA should have some revenue

Contact Info

Questions: Application Portal -> CPRIT Help Desk

Phone: 866-941-7146

Email: Help@CPRITGrants.org

Monday through Friday, 7 a.m. to 4 p.m. CT

Questions: Application Content and RFAs:

Rosemary French, Senior Program Manager, Product Development

Phone: 512-305-7676

Email: rfrench@cprit.texas.gov

CPRIT Website: https://www.cprit.texas.gov

Q&A

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